



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Dana Ault-Riche, *et. al* Art Unit : 1639
Serial No. : 09/910,120 Examiner : My-Chau T. Tran
Filed : July 18, 2001 Confirmation No.: 1666
Cust. No. : 20985
Title : COLLECTIONS OF BINDING PROTEINS AND TAGS AND USES THEREOF
FOR NESTED SORTING AND HIGH THROUGHPUT SCREENING

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 C.F.R. § 1.144

PETITION FROM REQUIREMENT FOR RESTRICTION

Dear Sir:

Applicant hereby petitions under 37 C.F.R. §1.144 from a Requirement for Restriction and a Requirement for Election of Species in the above-captioned application. Applicant respectfully requests reconsideration and removal of the Restriction Requirement as between Groups I and III. Further, Applicant petitions for rejoinder and examination of claims 11-16, 23, 25-32, 34-35, 94-95 and 99 with the claims of Group I.

STATEMENT OF FACTS

The Restriction Requirement mailed October 2, 2002, set forth ten (10) Groups. Applicant elected, with traverse, Group I in an Election, mailed December 27, 2002. Applicant traversed the Restriction Requirement as between Groups I and II, I and III, and as between Groups VIII and IX. In the Office Action mailed April 8, 2003, the Examiner deemed

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Date of Deposit April 07, 2004

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Stephanie Seidman
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Applicant's arguments unpersuasive, and set forth an additional election of species to select a single species comprising a capture agent and an oligonucleotide compound. Applicant elected with traverse, species where the oligonucleotide comprises a polypeptide-encoding region (i.e., has formula 5'-E_m-3'), where each polypeptide that binds to a capture agent is encoded by a region designated E_m that is at least about 16 nucleotides, and capture agents that are antibodies for search purposes.

In the Office Action mailed February 25, 2004, the Examiner deemed Applicant's arguments unpersuasive and the Restriction Requirement and Election of Species were made final. The Examiner withdrew claims 11-16, 23, 25-32, 34-35, 94-95 and 99 from consideration as being drawn to a non-elected species, because there is no allowable linking claim. Claims to Groups II and IV-X have been cancelled and thus, are not further addressed herein.

ARGUMENT

1. RESTRICTION REQUIREMENT

Applicant respectfully petitions for reconsideration and removal of the Restriction Requirement as between Groups I and III. It is respectfully submitted that claims of Groups I and III are related as a combination/subcombination for which a showing of two-way distinctness is required. Inventions that are related as a combination and subcombination are distinct and restriction may be proper only if it can be shown that the combination as claimed does not require the particulars of the subcombination as claimed for patentability and that the subcombination has utility by itself or in other combinations. See MPEP 808.05(c).

In this instance, the restriction is improper because the combination as claimed requires the particulars of the subcombination for patentability. Group I, the subcombination, is directed to a combination of elements, and Group III, the combination, is directed to the combinations of Group I plus a computer system. For example, Claim 1 of Group I (the subcombination) is directed to a combination containing a) a collection of capture agents; and b) a plurality of oligonucleotides. The oligonucleotides encode pre-selected polypeptides to which the capture agents bind.

Claim 1 A combination, comprising:
a plurality of capture agents, wherein each capture agent specifically binds to a polypeptide; and
a plurality of oligonucleotides that each comprises a sequence of nucleotides that encodes a preselected polypeptide,
wherein:
the preselected polypeptides encoded by the oligonucleotides comprise the polypeptides to which the capture agents bind; and
the oligonucleotides are single-stranded, double-stranded or partially double-stranded.

Claim 49 of Group III (the combination) is directed to a system containing a combination of claim 1 and a computer system for analyzing results of sorts using the combination.

Claim 49 A system for sorting collections of molecules, comprising:
a) a combination of claim 1; and
b) a computer system with software for analyzing results of sorts.

Thus, claim 49 of Group III is directed to claim 1 plus a computer system. As claimed, the computer system is not the basis for the patentability of claim 49; patentability can be based on the combinations of claim 1.

The Examiner urges that Group III does not require the particulars of the subcombination (Group I) for patentability because the subcombination "does not need to be the claimed array (i.e. combination) comprising capture agents and oligonucleotides." As an example, the Examiner points to Example I of the instant specification describing combinations of antibodies and protein tags, and additionally, arrays containing combinations such as receptors and ligands and proteins and peptidomimetics.

Even if the Examiner was correct in noting another utility for the subcombination (Group I), restriction as between Groups I and III is still not proper. As noted above, restriction between a combination/subcombination requires two-way distinctness. A showing that the subcombination (Group I) has utility in other combinations does not satisfy the test. Not only must the subcombination have utility in other combinations, the combination as claimed must be shown not to require the particulars of the subcombination for patentability. This showing has not been made with respect to the combination (Group III) at issue. As claimed, the combination

(Group III) does require the particulars of the subcombination for patentability. Therefore, two-way distinctness is not shown.

Furthermore, if the claims are restricted into these two groups, applicant ultimately could be granted two patents that expire on different dates: one that includes claims directed to the combinations of Group I and another with claims directed to systems of Group III that include the combinations of Group I. If the claims to the combination (Group III) issued first, a later issuing patent encompassing the subcombination of Group I could not be held to constitute obvious-type double patenting over the earlier issuing patent (and vice versa). See MPEP 806, paragraph 3, which states:

[w]here inventions are related as disclosed but are not distinct as claimed, restriction is never proper. Where restriction is required by the Office double patenting cannot be held, and thus, it is imperative the requirement should never be made where related inventions as claimed are not distinct.

See, also MPEP 804.01, which states:

35 U.S.C. 121 authorizes the Commissioner to restrict the claims in a patent application to a single invention when independent and distinct inventions are presented for examination. The third sentence of 35 U.S.C. 121 prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent. The 35 U.S.C. 121 prohibition applies only where the Office has made a requirement for restriction. The prohibition does not apply where the divisional application was voluntarily filed by the applicant and not in response to an Office requirement for restriction. This apparent nullification of double patenting as a ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restrictions where the claims define essentially the same invention in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.

As noted above, if Group I (the subcombination) is deemed patentable then Group III (the combination) is patentable. Since restriction of such Groups is improper, reconsideration and withdrawal of the restriction requirement as between Group I and Group III are, therefore, respectfully requested.

2. WITHDRAWAL OF CLAIMS TO NON-ELECTED SPECIES

Applicant respectfully petitions for reconsideration of the withdrawal of claims 11-16, 23, 25-32, 34-35, 94-95 and 99 from consideration and Applicant requests rejoinder of these claims with Group I for examination.

In response to the request for election of species, Applicant elected antibodies as capture agents and elected an oligonucleotide that contains a sequence of nucleotides that encodes a polypeptide to which a capture agent binds, an "E_m" region, of at least 16 nucleotides in length. Independent claim 1 is directed to a combination of a) a collection of capture agents; and b) a plurality of oligonucleotides, where the oligonucleotides encode the polypeptides to which the capture agents bind. Thus, within the election of species, claim 1 encompasses a combination of a) a collection of capture agent antibodies; and b) a plurality of oligonucleotides, where the oligonucleotides contain sequences of nucleotides that encodes encode the polypeptides to which the capture agents bind, E_m regions, that are at least 16 nucleotides in length.

Claims 11-14, 34 and 35 are directed to combinations of claim 1 where the oligonucleotides contain an E_m region and a divider region. Claims 15, 16, 23, 26-32, 94, 95 and 99 are directed to combinations of claim 1 where the oligonucleotides contain an E_m region, a divider region and a common region. Claim 25 is directed to combinations of claim 1 where the oligonucleotides contain an E_m region and a common region.

Each of the withdrawn claims includes an E_m region with additional specified regions. Thus, if the combination containing capture agents and the oligonucleotides E_m are patentable, then a combination that contains oligonucleotides E_m with additional regions specified must necessarily be patentable. Therefore, claims 11-16, 23, 25-32, 34-35, 94-95 and 99 should be examined along with claim 1 and claims dependent thereon in Group I.

3. ADDITIONAL ISSUE FOR CONSIDERATION

Applicant would like to bring the following to the attention of the Patent Office. In the Office Action mailed February 25, 2004, the Examiner alleges that the election of species is proper because the combination comprises several distinct species within each genus of capture agents and oligonucleotides. Further, the Examiner alleges that the presently claimed combination can be interpreted in two ways: (a) a combination of capture agents and oligonucleotides that encode a pre-selected polypeptide to which the capture agents binds; it is alleged that oligonucleotides are "attached" to the capture agent, and a combination of an array of probes (capture agents) that bind to the analyte (oligonucleotide) or an array of probes that comprise combination of capture agent and oligonucleotide wherein they are 'link' (i.e. the point of attachment to the capture agent).

Applicant respectfully submits that the Examiner has based this reasoning on a misreading of the claims. The Examiner has inserted words into the claims that are not recited in the claims, nor recited in the specification. Thus, the Examiner has substantially altered the meaning of the claims. Independent claim 1 and claims dependent thereon do not recite oligonucleotides "attached" or "link" to capture agents. No such terms appear in the claims or in the specification with respect to capture agents and oligonucleotides. The claims are directed to capture agents that bind polypeptide tags (not oligonucleotides). The tags are encoded by the oligonucleotides. Thus, there is "no point of attachment" or "link" between the capture agents of the collection and the plurality of oligonucleotides. In each of the claimed combinations, the capture agents bind to the polypeptides encoded by the E_m region of the oligonucleotides.

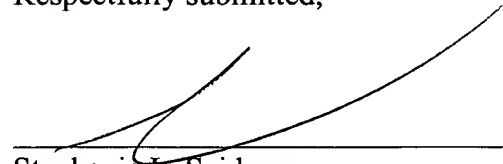
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• Applicant : Dana Ault-Riche, *et. al*
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Attorney's Docket No.: 25885-1751
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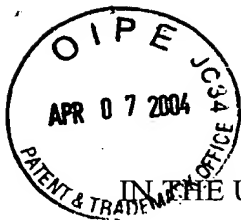
In view of the remarks herein, reconsideration of the requirement for restriction and examination of all pending claims on the merits are respectfully requested.

Respectfully submitted,



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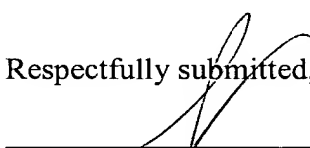
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TRANSMITTAL

Transmitted herewith is a Petition pursuant to 37 C.F.R. §1.144 from a Requirement for Restriction with a check for the requisite fee (\$130) for filing in connection with the above-identified application.

☒ [X] The Commissioner is hereby authorized to charge any fees that may be due under 37 C.F.R. §§ 1.16-1.17 in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed

Respectfully submitted,


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